IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF NEW YORK

NOVARTIS PHARMA AG, NOVARTIS PHARMACEUTICALS CORPORATION, and NOVARTIS TECHNOLOGY LLC, Plaintiffs, v. REGENERON PHARMACEUTICALS, INC., Defendant.	Civil Action No. 1:20-cv-00690 (TJM-CFH) **DEMAND FOR JURY TRIAL**

FIRST AMENDED COMPLAINT AND ANSWER TO COUNTERCLAIM

Plaintiffs Novartis Pharma AG ("NPAG"), Novartis Pharmaceuticals Corporation ("NPC") and Novartis Technology LLC ("NT") (collectively, "Plaintiffs" or "Novartis") bring this action against Defendant Regeneron Pharmaceuticals, Inc. ("Regeneron") for infringement of U.S. Patent No. 9,220,631 ("the '631 patent").

INTRODUCTION

1. Wet age-related macular degeneration ("Wet AMD") is the leading cause of vision loss in individuals over 50. Drugs called vascular endothelial growth factor ("VEGF")-antagonists can be used to treat Wet AMD and other devastating ophthalmic conditions, but must be injected into the eye by a physician. The injection itself carries a risk of complications including infection, inflammation, introduction of particles into the eye, and even potentially blindness. To address the problems associated with injection of VEGF-antagonists into the eye, Novartis scientists invented groundbreaking pre-filled, sterilized syringes that permit more safe, effective and

efficient injections of VEGF-antagonists into the eye. These inventions are disclosed and claimed in the '631 patent.

2. Regeneron manufactures and markets in the United States a product called EYLEA® ("EYLEA®"), which is provided in vial and pre-filled syringe ("PFS") presentations ("EYLEA® PFS"), both of which contain the VEGF-antagonist aflibercept. EYLEA® PFS unlawfully uses Novartis's patented syringe technology and infringes the '631 patent.

THE PARTIES

3. Plaintiff Novartis Pharma AG is a company organized and existing under the laws of Switzerland, with a principal place of business at Forum 1 Novartis Campus, CH-4056 Basel, Switzerland.

4. Plaintiff Novartis Pharmaceuticals Corporation is a Delaware corporation with a principal place of business at One Health Plaza, East Hanover, New Jersey, 07936.

5. Plaintiff Novartis Technology LLC is a Delaware corporation with a principal place of business at One Health Plaza, East Hanover, New Jersey, 07936.

6. On information and belief, Regeneron is a New York corporation with its principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591.

7. On information and belief, Regeneron has an established facility in this District at 81 Columbia Turnpike, Rensselaer, New York 12144.

JURISDICTION AND VENUE

8. This is an action for patent infringement arising under 35 U.S.C. § 271.

9. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

10. The Court has personal jurisdiction over Regeneron because it is domiciled in New York.

11. Venue is proper in this District under 28 U.S.C. §§ 1400(b) and 1391. On information and belief, Regeneron has a regular and established place of business in Rensselaer, New York, which is within this District, and Regeneron has committed acts of infringement within the District.

BACKGROUND

12. On December 29, 2015, the United States Patent and Trademark Office duly and legally issued the '631 patent, entitled "Syringe," to inventors Juergen Sigg, Christophe Royer, Andrew M. Bryant, Heinrich M. Buettgen, and Marie Picci. A true and correct copy of the '631 patent is attached as Exhibit A.

13. The '631 patent is valid and presumed valid under 35 U.S.C. § 282. The '631 patent is also enforceable.

14. Novartis owns the right, title and interest in the '631 patent necessary to bring this action, including the exclusive right to enforce the patent in the United States.

15. The '631 patent discloses and claims certain novel terminally sterilized, pre-filled syringes that include VEGF-antagonists. Claim 1, for example, reads as follows:

> 1. A pre-filled, terminally sterilized syringe for intravitreal injection, the syringe comprising a glass body forming a barrel, a stopper and a plunger and containing an ophthalmic solution which comprises a VEGF-antagonist, wherein:
>
> (a) the syringe has a nominal maximum fill volume of between about 0.5 ml and about 1 ml,
>
> (b) the syringe barrel comprises from about 1 µg to 100 [µ]g silicone oil,
>
> (c) the VEGF antagonist solution comprises no more than 2 particles > 50 µm in diameter per ml and wherein the syringe has a stopper break loose force of less than about 11N.

(the '631 patent (Exhibit A) at cl. 1).

16. EYLEA® PFS is a syringe pre-filled with the VEGF-antagonist aflibercept and approved for the treatment of, among other things, Wet AMD. On information and belief, EYLEA® PFS is covered by one or more claims of the '631 patent.

COUNT I: INFRINGEMENT OF THE '631 PATENT

17. Novartis realleges and incorporates by reference the allegations in the preceding paragraphs as though fully stated herein.

18. Regeneron was found by an administrative law judge of the International Trade Commission ("ITC") in a Section 337 Investigation captioned *Certain Pre-filled Syringes for Intravitreal Injection and Components Thereof*, Inv. No. 337-TA-1207 (U.S. ITC Jun. 19, 2020) (the "ITC Investigation") to infringe several claims of the '631 patent.

19. Regeneron's EYLEA® PFS satisfies each and every element, either literally or under the doctrine of equivalents, of one or more claims of the '631 patent, including at least claim 1 as follows.

20. EYLEA® PFS is a pre-filled, terminally sterilized syringe for intravitreal injection.

21. The EYLEA® PFS syringe comprises a glass body forming a barrel, a stopper, and a plunger.

22. The EYLEA® PFS contains an ophthalmic solution which comprises a VEGF-antagonist. The drug product in the EYLEA® PFS is a solution of the VEGF-antagonist aflibercept provided at a strength of 40 mg/mL, and the approved indications for EYLEA® PFS are ophthalmic.

23. The EYLEA® PFS has a nominal maximum fill volume of between about 0.5 mL and about 1 mL.

24. The EYLEA® PFS barrel comprises about 1 µg to 100 µg silicone oil.

25. The VEGF antagonist solution in the EYLEA® PFS comprises no more than 2 particles >50 μm in diameter per mL.

26. The EYLEA® PFS has a stopper break loose force of less than about 11N.

27. The EYLEA® PFS is presented in one blister pack containing one EYLEA® 2 mg/0.05 mL sterile, single-dose pre-filled glass syringe.

28. The VEGF-antagonist aflibercept in the EYLEA® PFS is administered by intravitreal injection.

29. Since at least December 2019, Regeneron has made, used, offered for sale, sold, and or imported, and continues to make, use, offer for sale, sell, and/or import, the infringing EYLEA® PFS product in the United States. Such conduct constitutes direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '631 patent under 35 U.S.C. § 271(a).

30. Regeneron has actively encouraged infringement of at least claim 24 of the '631 patent by providing physicians with instructions to administer EYLEA® PFS to treat patients suffering from choroidal neovascularization, wet age-related macular degeneration, macular edema secondary to retinal vein occlusion, choroidal neovascularization secondary to pathologic myopia, diabetic macular edema, diabetic retinopathy, and/or proliferative retinopathy. On information and belief, the physicians have infringed and will continue to infringe at least claim 24 by treating such patients in this manner.

31. Regeneron has actively induced infringement of one or more claims of the '631 patent, either literally or under the doctrine of equivalents, in violation of 35 U.S.C. § 271(b).

32. Regeneron's unlawful infringement activities have caused and will continue to cause Novartis substantial harm.

33. The harm Novartis has suffered and will continue to suffer is irreparable and cannot be sufficiently compensated through monetary damages. This harm includes, but is not limited to, loss of business opportunities, loss of market share, price erosion, loss of goodwill, and direct and indirect competition. Accordingly, Novartis is entitled to preliminary and permanent injunctive relief. The public interest would not be disserved by injunctive relief.

34. Regeneron's infringement of the '631 patent is willful, justifying the assessment of treble damages pursuant to 35 U.S.C. § 284.

35. Regeneron has admitted in discovery responses in the ITC investigation that it has been aware of the '631 patent since its issuance, and was aware of the application that eventually issued as the '631 patent even before that time.

36. In a complaint it filed against Novartis in the Southern District of New York, Regeneron alleged that in late 2013, "Vetter contacted Regeneron, claiming that Novartis had a pending patent application covering EYLEA PFS" and that Vetter offered a sublicense "for the application that would eventually become the '631 patent." Complaint ¶ 166, *Regeneron Pharms., Inc. v. Novartis Pharma AG et al.*, No. 20-cv-5502 (S.D.N.Y. July 17, 2020) (ECF No. 1).

37. Regeneron also alleged in the SDNY complaint that once the '631 patent issued Vetter again approached Regeneron with the offer to sublicense Novartis's PFS technology. *Id.* ¶ 18.

38. Regeneron further alleged that in February 2014 Regeneron specifically requested from Vetter "information regarding the process covered by the '631 patent." *See id.* ¶ 179.

39. Regeneron has marketed its EYLEA® PFS with the knowledge that it infringed one or more claims of the '631 patent. In the ITC Investigation, Regeneron conceded that the EYLEA® PFS infringed multiple claims of the '631 patent. On information and belief, Regeneron

knew or should have known that the EYLEA® PFS infringed multiple claims of the '631 patent before it conceded that fact in the ITC Investigation and before this suit was filed.

40. On information and belief, Regeneron also had no reasonable basis for believing that the '631 patent was invalid or otherwise unenforceable.

41. Internal Regeneron documents indicate that Regeneron knew that it would not have freedom to operate unless it took a license to the '631 patent. Accordingly, Regeneron knew or should have known that marketing EYLEA® PFS would infringe the '631 patent and, on information and belief, did not believe that the '631 patent was invalid or unenforceable.

42. On information and belief, despite Regeneron's knowledge of the '631 patent and that it required a sublicense to the '631 patent in order to have freedom to operate for its EYLEA® pre-filled syringe, Regeneron declined to license the '631 patent and instead chose to willfully infringe it by launching the EYLEA® pre-filled syringe product in December 2019.

PRAYER FOR RELIEF

WHEREFORE, Novartis respectfully requests that this Court enter judgment in its favor and against Regeneron as follows:

A. A judgment that Regeneron has infringed the '631 patent;

B. An award of damages to Novartis for Regeneron's infringement, together with pre- and post-judgment interest and costs pursuant to 35 U.S.C. § 284, including supplemental damages for any continuing post-verdict infringement up until entry of the final judgment;

C. Treble damages pursuant to 35 U.S.C. § 284;

D. A finding that this case is "exceptional" under 35 U.S.C. § 285 and an award of attorneys' fees and costs;

E. Orders preliminarily and permanently enjoining Regeneron and its officers, employees, agents, servants, and those in privity with them from continuing to infringe the ’631 patent; and

F. Any further and additional relief as this Court deems just and proper.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Novartis demands a trial by jury on all issues triable by jury.

ANSWER TO COUNTERCLAIM

Novartis Pharma AG, Novartis Pharmaceuticals Corporation, and Novartis Technology LLC (collectively, "Novartis") hereby answers the Counterclaim of Regeneron Pharmaceuticals, Inc. ("Regeneron") as follows:

THE PARTIES

1. Novartis is without knowledge or information to answer the allegations in this paragraph, on and that basis denies them.

2. Admitted that Novartis Pharma AG is a corporation organized and existing under the laws of Switzerland, with a principal place of business at Forum 1 Novartis Campus, CH-4056 Basel, Switzerland.

3. Admitted that Novartis Pharmaceuticals Corporation is a corporation organized and existing under the laws of Delaware, with a principal place of business at One Health Plaza, East Hanover, New Jersey, 07936.

4. Admitted that Novartis Technology LLC is a corporation organized and existing under the laws of Delaware, with a principal place of business at One Health Plaza, East Hanover, New Jersey, 07936.

JURISDICTION AND VENUE

5. This paragraph contains conclusions of law to which no response is required.

6. This paragraph contains conclusions of law to which no response is required.

7. This paragraph contains conclusions of law to which no response is required. For purposes of this action only, Novartis does not contest personal jurisdiction in this District.

8. This paragraph contains conclusions of law to which no response is required. For purposes of this action only, Novartis does not contest venue in this District.

COUNTERCLAIM I
(Declaratory Judgment of Invalidity of the '631 Patent)

9. Admitted that Novartis owns the right, title and interest in the '631 patent necessary to bring its First Amended Complaint in this action, including the exclusive right to enforce the patent in the United States. Admitted that on December 29, 2015, the United States Patent and Trademark Office duly and legally issued the '631 patent, entitled "Syringe." Admitted that a true and correct copy of the '631 patent was attached to Novartis's Complaint (and Novartis's Amended Complaint) as Exhibit A. Admitted that the '631 patent was assigned by the named inventors to Novartis Pharma AG. Admitted that in November 2020, the U.S. Patent and Trademark Office was notified of an assignment transferring ownership of the '631 patent to Novartis Technology LLC, Novartis Pharmaceuticals Corporation, and Novartis Pharma AG, the three Novartis plaintiffs. The remainder of this paragraph contains conclusions of law to which no response is required.

10. Admitted that Novartis alleges that Regeneron's EYLEA® PFS infringes at least one claim of the '631 Patent.

11. Admitted that this paragraph purports to reproduce claim 1 of the '631 patent.

12. Denied.

13. This paragraph contains conclusions of law to which no response is required.

14. Admitted that Regeneron purports to state a claim for declaratory judgment, but denied that Regeneron is entitled to the declaratory relief it seeks. This paragraph contains conclusions of law to which no response is required.

15. Denied.

RESPONSE TO PRAYER FOR RELIEF

No response is required to Regeneron's prayer for relief. To the extent that a response is deemed required, Novartis denies that Regeneron is entitled to the relief it seeks or to any relief at all for the allegations made in the Counterclaim. Regeneron's prayer should therefore be denied in its entirety and with prejudice.

Dated: August 2, 2021

By:

BOND, SCHOENECK & KING, PLLC

s/ George R. McGuire

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